varied from 19 for warts, to 27 for CIN 3 and approximately 450 for cancer and was similar for the differently aged cohorts. Results were sensitive to the duration of vaccine efficacy and coverage. If vaccine coverage was as low as 30%, the NNV for warts, CIN 3 and cancer would increase to 50, 57 and 1115 respectively. If the duration of efficacy was only 10 years instead of a lifetime, the NNV would increase to 62 for warts, 67 for CIN 3 and over 1100 for cancer. **CONCLUSION:** These analyses suggest that the NNV for warts and cervical pre-cancer using a quadrivalent HPV vaccine is low, but will depend on the duration of vaccine efficacy as well as coverage.

PCN47

EVALUATION OF FACTOR STRUCTURE AND RELIABILITY OF THE FUNCTIONAL ASSESSMENT OF CANCER THERAPY—KIDNEY SYMPTOM INDEX

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OBJECTIVES: The Functional Assessment of Cancer Therapy—Kidney Symptom Index (FKSI) is a 15-item scale that was developed and validated to assess symptoms and concerns of advanced kidney cancer patients. The aim of this study was to evaluate the factor structure of FKSI for possibly useful subscales and assess the reliability of the sub-scales. **METHODS:** Data for this study were obtained from a phase III clinical trial of 903 advanced renal cancer patients. Patients were administered FKSI questionnaire at baseline. Baseline data were analyzed using exploratory factor analysis with oblique rotation (promax) to evaluate the dimensional structure of FKSI. The internal consistency of the subscales and overall scale was assessed using Cronbach's alpha. **RESULTS:** Four factors were identified consisting of 13 of the 15 items of FKSI. The first factor had two items related to pain symptoms; the second factor had two items related to respiratory symptoms; the third factor had five items related to general symptoms of the disease and; the fourth factor had four items related to quality of life. All four factors had good reliability (alphas > 0.70). The internal consistency of the overall 13-item scale was excellent (alpha = 0.83). **CONCLUSION:** A four-factor solution consisting of 13 items could easily be labeled with clinically-meaningful concepts, indicating the possibility of four underlying dimensions of kidney cancer symptomatology: pain, respiratory, general symptoms and quality of life. Findings supported the internal consistency of four sub-scales and overall 13-item scale. Sub-scale scores and the total index are reliable and valid measure that can be used to determine the effect of drug therapies on specific symptoms and concerns of advanced kidney cancer.

PCN48

STANDARD GAMBLE TECHNIQUES FOR THE MEASUREMENT OF TREATMENT RELATED TOXICITY IN ONCOLOGY: APPLICATION TO ADVANCED STAGE PROSTATE CANCER

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OBJECTIVES: To assess Australian men's preferences for health states (HS) specific to advanced stage prostate cancer (APC) including baseline diagnoses of APC, response, no response, disease progression and especially treatment-related toxicities by severity apart from other components of the HS which is methodologically different. **METHODS:** FACT-P QOL data from patients with APC were used to compose HS narratives consisting of physical, social, emotional, functional well-being, additional concerns domains. Treatment-related mild, moderate, severe and life-threatening toxicities were described separately. 100 Australian men were recruited and interviewed using standard gamble techniques (SG). Baseline diagnoses of APC, response, no response and disease progression using SG as usual with oscillating risks of perfect health (1) and immediate death (0) as anchors OR the HS narrative with 100% certainty. For toxicities, however, the true trade-off is treatment response with an associated risk of toxicity OR no treatment and remain with 100% certainty at baseline APC. This obtains how much chance of response a man needs to be indifferent to the corresponding chance of toxicity by severity. **RESULTS:** SG regression results were 0.506 ($p < 0.01$) for baseline APC, 0.602 ($p < 0.01$) for response, 0.502 ($p < 0.01$) for no response, and 0.318 ($p < 0.01$) for disease progression. The trade-off between a chance of treatment response with a corresponding chance of mild, moderate, severe, or life-threatening toxicity yielded utility scores of 0.794 ($p < 0.01$), 0.715 ($p < 0.01$), 0.466 ($p < 0.01$), and 0.257 ($p < 0.01$), respectively. **CONCLUSION:** Men need at least a 21%, 28%, 55% or 74% chance of treatment response to be indifferent to treatment related toxicity depending on severity. These measured values are more appropriate for Quality-adjusted Time Without Symptoms of disease and Toxicity (Q-TWiST) analysis where time without disease progression is rewarded while disease progression with toxicities is penalized by applying a utility weights for disease progression and time with toxicity than the usual arbitrary ones.

PCN49

LINGUISTIC VALIDATION OF THE FACT-HEAD AND NECK IN 8 LANGUAGES FOR INDIA

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OBJECTIVES: The purpose of this study was to translate and linguistically validate the Functional Assessment of Cancer Therapy—Head and Neck V. 4 (FACT-H&N) for Gujarati, Hindi, Kannada, Malayalam, Marathi, Tamil, Telugu and Urdu translations. **METHODS:** The FACT-H&N was originally developed through patient and expert interviews, and validation studies. The FACT-H&N was translated according to the standard FACIT methodology: 2 forward translations, a reconciled version of the 2 forwards, back-translation to English, 3 independent reviews by bilingual experts, and harmonization across all languages. The study sample included 120 patients from 8 regions of India. Patients diagnosed with any type of head and neck cancer completed the translated FACT-H&N and then participated in cognitive debriefing interviews. Statistical analyses (descriptive statistics and reliability analyses) were performed on the quantitative data, and the participant comments were analyzed qualitatively. **RESULTS:** Most of the languages showed acceptable reliability ranging from 0.69 to 0.87 for the H&N subscale despite the small sample size with the exception of Kannada (0.13) and Tamil (0.56). There were no negative patient comments related to the H&N specific items. However, when item-total correlations were examined, it was found that some items performed poorly across some languages. They included mouth dryness, trouble breathing, and communication with others. Of these, only the item about communication seemed to indicate a cultural issue affecting the item's relevance. Small changes were made to the Telugu translation but not to the other languages. **CONCLUSION:** The FACT-H&N has shown good reliability and linguistic validity with 8 language versions. We consider these translations to be acceptable for use in interna-

tional research and clinical trials. These results contribute to a better understanding of how QOL issues are perceived by head and neck patients in India, strengthening the cross-cultural comparability of this instrument.

PCN50

CHALLENGES AND LIMITATIONS OF IDENTIFYING PRESCRIPTION TREATMENT PATTERNS FOR PATIENTS WITH METASTATIC BREAST CANCER USING COMMERCIALLY INSURED CLAIMS DATABASES

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OBJECTIVES: The objective of this study was to illustrate the challenges and limitations of using claims data and developing algorithms to study prescription patterns for metastatic breast cancer (MBC) in patients previously treated with anthracycline and taxane. **METHODS:** Extract from the PharMetrics Integrated Outcomes Database between Janaury 1999 and June 2005 was used. Lacking a diagnosis code for MBC, we defined the condition = 2 ICD-9 codes for breast cancer (BC) and 1 ICD-9 code for distant metastases. Drug exposure was defined as °Ý1 NDC/J-code for anthracycline and taxane. A treatment interval of 21 days was created to account for a high proportion of missing or zero values for days supply of chemotherapy agents recorded in claims database and to determine treatment duration assigned to all agents from reference date, defined as the dispense date of the first anthracycline or taxane prescription, whichever occurred later. Consecutive intervals with same agents were collapsed into one regimen regardless of sequence; otherwise intervals were treated as separate regimens. **RESULTS:** Among 38,588 patients with °Ý2 BC diagnoses, 5017 (13%) exhibited °Ý1 diagnoses for distant metastasis, 1121 (3%) were previously exposed to an anthracycline and a taxane, and 1028 met other criteria (age°Ý18 years and eligibility °Ý6 months). Of the 1028, 67% did not receive sequential therapy, and 80% of these had non-chemotherapy claims 90 days following last chemotherapy, with a mean post chemotherapy duration of 489 ± 430 days. Among the 33% who received sequential therapy, the mean number of sequential therapies was 2.8 ± 2.7 with mean duration of 66 ± 82 days. **CONCLUSION:** The current analysis illustrates a method of using algorithms to define MBC diagnoses and treatment duration in claims-based treatment pattern studies. However, such algorithms must be validated against the patients' medical records in order to assess the respective accuracy of disease and treatment pattern identification.

PCN51

METHODS AND APPLICATION OF DATA COLLECTION TECHNOLOGY IN THE ELECTRONIC VELCADE® OBSERVATIONAL STUDY (EVOBS)

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OBJECTIVES: eVOBS is an international, non-interventional, observational study of clinical and economic outcomes in patients who receive VELCADE for the approved indication in multiple myeloma. **METHODS:** Patients who initiate VELCADE therapy for the approved indication are eligible for the study. Retrospective treatment data from 12 months prior to study entry and prospective treatment data for 36 months are collected via a secure, privacy-protected website. At study entry, submitted data are electronically screened against validation rules that have been prospectively established in consultation with multiple myeloma treatment specialists and data analysis specialists. These rules were designed to prevent missing data, duplicate data and data outside pre-established, logical ranges. Initial inputs require study center confirmation before the system uploads data to the central database. During the study, if there is any data that is inconsistent with previously submitted entries, study sites submit corrections via an audited online data change request system. Finally, an ongoing audit process is used to validate the quality of the data uploaded to the central database. This process uses monthly reports to identify potential inconsistencies within the dataset after data has been validated at entry. **RESULTS:** Uploaded data undergoes quality control checks, requiring adjustment by physicians to be minimal. Audit reports help to redress data entry training issues, further enhancing data accuracy. Analysis is only conducted on patients after resolution of outstanding supplemental data queries. **CONCLUSION:** The goal of this study is document outcomes in a generalizable, representative patient cohort. This information will broaden our understanding of the use of VELCADE in typical clinical practice, outside of the interventional clinical trial setting. This largely automated three-stage quality control process streamlines the implementation of this non-interventional, observational research and permits the inclusion of patients from a broad geographic region. The study method allows for faster analysis and presentation of robust, pragmatic outcomes data.

CANCER—Patient-Reported Outcomes

PCN52

COMPARISON OF IMPACT OF ELEVEN TYPES OF ADVANCED CANCER ON QUALITY OF LIFE

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OBJECTIVES: To compare the impact of 11 types of cancer on different domains of HRQL using the FACT-G and EQ-VAS. **METHODS:** Patients diagnosed with advanced cancer of the bladder, brain, breast, colorectal, head/neck, hepatobiliary/pancreas, kidney, lung, lymphoma, ovary or prostate completed HRQL assessments. HRQL was compared between patient groups for each subscale of the FACT-G, i.e., physical well-being (PWB), social/family wellbeing (SWB), emotional well-being (EWB) and functional well-being (FWB), and EQ-VAS, unadjusted and adjusted for age/gender using regression models. **RESULTS:** Approximately 50 patients were recruited for each cancer group (total n = 534). Mean age (SD) ranged from 52(11) (brain) to 70(8) (prostate). Unadjusted mean (SD) scores for PWB ranged from 66.8(17.2) (head/neck) to 78.1(21.3) (prostate); for SWB ranged from 81.4(19.1) (brain) to 90.6(22.0) (kidney); for EWB ranged from 61.7(16.0) (breast) to 72.0(16.9) (prostate); and FWB ranged from 54.7(20.2) (head/neck) to 67.8(18.5) (prostate). EQ-5D VAS mean scores were lowest for head/neck [61.8(21.7)] and highest for colorectal [72.0(17.1)]. Compared to lymphoma, adjusting for age/gender, PWB mean scores (SE) were significantly lower for patients with head/neck [–10.9(4.0)], hepatobiliary [–10.9(4.0)], and kidney [–9.7(4.0)]. FWB mean scores were significantly lower for head/neck [–10(3.2)], hepatobiliary [–8.9(3.1)], bladder [–7.7(3.6)], and lung [–6.7(3.1)]. Patients 65 years and older had mean (SE) scores for PWB = +9.2(2.1), EWB = +2.9(1.0), FWB = +3.1(1.6), and EQ VAS = +4.5(2.1) compared to patients aged 45 to 64. For median rank across all FACT subscales, hepatobiliary ranked worst and prostate the highest. Adjusting for age and gender, hepatobiliary ranked worst and lymphoma highest based on FACT median scores, while breast ranked lowest and colorectal highest based on mean VAS scores. **CONCLUSION:** Older